JUN 25 2014

510(k) SUMMARY

Submitter:

Parkell, Inc.
300 Executive Drive
Edgewood, NY 11717
TEL: 631-249-1134
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Contact:

Robert E. Burke, VP of Operations
Parkell, Inc.
300 Executive Drive
Edgewood, NY 11717

Submission Date: 2 July 2013

Trade Name: Absolute Dentin II

Common Name: Composite Resin Core Material

Classification Name: Material, Tooth Shade, Resin (§872.3690)

Classification Product Code: EBF

Predicate Devices: D/C CORE MATERIAL (K010475), BUILD-IT FR (K000211), DC CORE (K984097)

Device Description: A dual-cure, composite resin, core build-up material that is usually used to restore missing tooth structure for which a dental restoration, usually a crown, is fabricated. It is substantially equivalent to many predicate materials that include self-, light-, and dual-cure types. This material incorporates fluoride-containing (trace amounts) glass filler particles. No Bisphenol-A or its precursors are used in the manufacturing process. The material is supplied in light-safe dual-barrel cartridges.

Indications for Use: Absolute Dentin II is a dual-cure, composite resin core build-up material that is usually used to restore missing tooth structure for which a dental restoration, usually a crown, is fabricated.

Tech. Characteristics: ABSOLUTE DENTIN II is a two-paste material generally supplied in a dual-barrel cartridge, each to be expressed through disposable mixing tips.

	Absolute Dentin II	Absolute Dentin
Indications for Use:	A dual-cure, composite resin core build-up material that is usually used to restore missing tooth structure for which a dental restoration, usually a crown, is fabricated.	A dual-cure, composite resin, core build-up material that is usually used to restore missing tooth structure for which a dental restoration, usually a crown is fabricated. This material is of the dual-cure variety and incorporates fluoride-containing glass filler particles.

Filler:	Silanated Silica	Silanated Silica
Matrix:	Methacrylate based resin matrix	Methacrylate based resin matrix
Compatibility:	Methacrylate based dental adhesives	Methacrylate based dental adhesives
Method of Cure:	Both self-cure & photo initiator	Both self-cure & photo initiator
Depth of Cure:	Tooth Shade – 5.2mm White Shade – 4.0mm	3.5 mm
Delivery Method:	5ml dual-barrel cartridge	50ml dual-barrel cartridge 10ml dual-barrel cartridge
Difference in Materials:	Bisphenol-A or its precursors were not used in the manufacturing process.	Contains Ethoxylated Bisphenol A Dimethacrylate

Biocompatibility: ABSOLUTE DENTIN II has been fully tested for biocompatibility in accordance with ISO and FDA guidelines. All tests were passed according to their protocols.

Standard	Test
ISO 10993-5, 2009, Biological Evaluation of Medical Devices – Part 5: Tests for *In Vitro* Cytotoxicity	L929 MEM Elution Test – ISO: Toxicon Final GLP Report #12-5730-G1, dated 12/24/12
ISO 10993-3, 2003, Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, Carcinogenicity and Reproductive Toxicity	Salmonella Typhimurium and Escherichia Coli Reverse Mutation Assay – ISO: Toxicon Final GLP Report #12-5730-G5, dated 1/10/2013
ISO 10993-10, 2010, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization	Intracutaneous Injection Test – ISO: Toxicon Final GLP Report #12-5730-G3, dated 1/11/2013
ISO 10993-10, 2010, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization	Kligman Maximization Test – ISO: Toxicon Final GLP Report #12-5730-G4, dated 2/19/2013
ISO 10993-10, 2010, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization	Oral Irritation Test – Acute Exposure – ISO: Toxicon Final GLP Report #12-5730-G2, dated 2/6/2013

Substantial Equivalence: Parkell's ABSOLUTE DENTIN II composite resin core material has similar indications, principles of operation and technological characteristics as the predicate devices. The minor differences in the device (primarily the absence of Bisphenol-A and its precursors in the manufacturing process) do not raise any new questions of safety or effectiveness. Thus, ABSOLUTE DENTIN II is substantially equivalent to its predicate devices.

Non-Clinical Performance Testing: Properties Tested- Flexural Strength, Compressive Strength, Surface Hardness, Working Time & Self-Curing Time

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 25, 2014

Parkell, Incorporated
Mr. Robert E. Burke
Vice President, Operations
300 Executive Drive
Edgewood, NY 11711

Re: K132115
Trade/Device Name: Absolute Dentin II
Regulation Number: 21 CFR 872.3690
Regulation Name: Material, Tooth Shade, Resin
Regulatory Class: II
Product Code: EBF
Dated: May 23, 2014
Received: May 27, 2014

Dear Mr. Burke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Absolute Dentin II

Indications for Use:

A dual-cure, composite resin core build-up material that is usually used to restore missing tooth structure for which a dental restoration, usually a crown, is fabricated.

Prescription Use ___X___ (21 CFR Part 801 Subpart D) AND/OR Over-The-Counter Use (21 CFR Part 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Sheena A. Green -S
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